Integra LifeSciences Corporation-Traditional 510(k)
INTEGRA® Freedom Wrist Arthroplasty System

MAR 2 4 2014

Section 5: 510(k) Summary

510(k) Summary

807.92(a)(1) – Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro NJ 08536
Name of Contact Person	Sally K. Wixson, VMD, RAC
Phone Number	(609) 936-2454
Fax Number	(609) 750 4277
Establishment Registration Number	3004608878
Date Prepared	July 8, 2013
807.92(a)(2) – Name of device	
Trade or Propriety Name	INTEGRA® Freedom Wrist Arthroplasty System
Common or Usual Name	Prosthesis, wrist, 3 part metal-plastic-metal articulation, semi-constrained
Classification Name	Wrist joint metal/polymer semi-constrained cemented prosthesis (21CFR §888.3800)
Classification Panel	Orthopedic
Regulation	Class II, under 21CFR §888.3800
Product Code	JWJ

807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed

- Universal Total Wrist System (K030037), cleared February 05, 2003
- Maestro™ Total Wrist (K042032), cleared October 7, 2004

807.92(a)(4) - Device description

The INTEGRA® Freedom Wrist Arthroplasty (IFW) System three part semi-constrained implant system designed to replace the radiocarpal joint (distal radius and proximal row of carpal bones) and is intended to alleviate pain while restoring functionality and mobility of the joint. IFW is intended for patients with intractable pain and loss function due to traumatic arthritis, osteoarthritis, rheumatoid arthritis, and trauma-induced osteoarthritis. The system consists of three major components:

- **Radial implant** – made from Cobalt Chromium Molybdenum Alloy (CrCoMo)
- **Carpal plate** - (includes two variable angle screws with locking caps) – made from Titanium Alloy
- **Carpal Poly bearing** – made from Ultra-High-Molecular-Weight Polyethylene (UHMWPe)

Portions of the radial implant and carpal plate have a titanium plasma sprayed coating. The implant system is provided with instrumentation necessary to complete the procedures for which the system is indicated. The components are intended to be

implanted together as a system, not individually as hemi-arthroplasty components and are intended for cemented fixation.
807.92(a)(5) – Intended Use of the device

Indications for Use	The INTEGRA® Freedom Wrist Arthroplasty System is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above. The INTEGRA® Freedom Wrist Arthroplasty System is intended for cemented use.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The proposed INTEGRA® Freedom Wrist Arthroplasty (IFW) system and the predicate systems (UTW and MTW) are designed to replace the radiocarpal joint and are intended to alleviate pain while restoring functionality and mobility of the joint. The overall design and materials of the proposed device and the predicate devices are similar. The systems consist of titanium, cobalt chrome, and Ultra-High-Molecular-Weight Polyethylene (UHMWPe) components which replace the articulation of the distal radius and proximal row of carpal bones of the wrist joint. The devices share three basic design elements in that they employ a radial component, a carpal bearing, and a carpal component. The carpal and radial components of the proposed and predicated devices have porous coated stems that are intended to be fixated into the bone with cement and utilize two screws to secure the carpal component into the carpal bones. The implant devices are provided with corresponding instrumentation.

The INTEGRA® Freedom Wrist Arthroplasty System has similar indication for use, intended use, and fundamental scientific technology as the predicate devices (K030037 and K042032). The proposed device utilizes similar materials and design features. The differences between the predicates and proposed device do not raise any new issues regarding safety and effectiveness; therefore, The INTEGRA® Freedom Wrist Arthroplasty System is considered substantially equivalent to the predicate devices.

807.92(b)(1-2) – Nonclinical Tests Submitted

Testing to verify the performance for the The INTEGRA® Freedom Wrist Arthroplasty System included the following:

- Fatigue Life Test
- Carpal Poly Bearing Removal
- Movement to Instability
- Screw Thread Verification:
  - Axial Screw Pull-out, Insertion Torque, Breaking Torque and Breaking Angle per ASTM F543
- Porous Coating Testing:
  - Shear Fatigue Strength per ASTM F1160

- Static Shear Strength per ASTM F1044
- Static Tensile per ASTM F1147
- Abrasion per ASTM F1978

The results of these performance tests met their respective acceptance criteria and demonstrate that the Integra® Freedom Wrist Arthroplasty System is safe for the intended use, and is substantially equivalent to the predicate device identified.

807.92(b)(3) – Conclusions drawn from non-clinical data

The design features, materials, intended use, and overall fundamental scientific technology of the Integra® Freedom Wrist Arthroplasty System are substantially equivalent to the predicate device. The safety and effectiveness of the Integra® Freedom Wrist Arthroplasty System is adequately supported by the substantial equivalence information, materials information, and performance data provided within this Premarket Notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

Integra LifeSciences Corporation
Mr. Frederic Testa
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K132250
Trade/Device Name: INTEGRA® Freedom Wrist Arthroplasty System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: February 20, 2014
Received: February 21, 2014

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Integra LifeSciences Corporation-Traditional 510(k)
INTEGRA® Freedom Wrist Arthroplasty System

Section 4: Indications for Use

Indications for Use

510(k) Number (if known): K132250

Device Name:

INTEGRA® Freedom Wrist Arthroplasty System

Indications For Use:
The INTEGRA® Freedom Wrist Arthroplasty System is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above. The INTEGRA® Freedom Wrist Arthroplasty System is intended for cemented use.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices